

10691459

Section iv - 510 (k) Summary

[Refer to 21 C.F.R § 807.92]

Submitted by: Respironics Novamatrix, LLC
5 Technology Drive
Wallingford, CT 06492

JUL 28 2009

Contact Person: Kevin Mader
Q.A. and Regulatory Manager
Phone: 203-697-6466

Date Prepared: 5/14/2009

Proprietary Name: Philips NM3 monitor

Common Name: multi-parameter monitor (monitoring spirometer, CO₂ monitor, pulse oximeter and cardiac output monitor with partial rebreathing valve).

Classification Name: Class II, 21 CFR 868.1850, 868.1400, 868.5675 and 870.2700

Predicate Device: NICO with MARS monitor, Model 7300 [510(k) K030886]

Description of Device: The Philips NM3 monitor is intended for non-invasive monitoring of the inspired and expired airflow and airway pressure of intensive care unit (ICU), anesthesia and emergency room (ER) patients, as well as capnography and pulse oximetry in all of these clinical settings. It is intended to serve the same purposes as the flow, carbon dioxide and pulse oximetry monitoring components of the predicate NICO with MARS monitor.

In the NM3 monitor as in the NICO system, combination CO₂ adapter/flow sensors (neonatal, pediatric, adult), combination adult CO₂ adapter/flow sensors with a partial rebreathing valve and flow sensors (infant/neonatal, pediatric/adult) are connected with a male pneumatic connector to the NICO monitor. Sidestream airway adapters and nasal cannulas are available which are connected with a sample cell connector to a receptacle on the LoFlo Module which can be interfaced to the NM3 monitor. All of these sensors are already legally marketed as accessories of 510(k) cleared Respironics-Novamatrix predicate devices. The pulse oximetry sensors are connected to the NM3 monitor via a connector on the front panel of the monitor. All of the pulse oximetry sensors are already legally marketed as accessories of 510(k) cleared Masimo predicate devices.

The principal function of the flow portion of combination sensors and flow sensors is to provide a differential pressure signal related to flow and airway pressure relative to atmospheric pressure. These sensors are often placed in the breathing circuit between the endotracheal tube and the ventilator circuit Y piece and may also be used in conjunction with a face mask or mouthpiece. The flow measurement portion of the NM3 monitor is contained in the Mercury module which consists of a microprocessor-based data acquisition system that measures flow, and pressure and interfaces with a Capnostat 5 CO₂ sensor. The CO₂ airway adapter portion of the combination sensors, allow the Respironics-Novamatrix CO₂ mainstream gas sensor, the Capnostat® 5, to attach to it and measure the concentration of CO₂ in the airway using infrared technology. When CO₂ measurements are combined with airway flow and volume measurements, other parameters such as CO₂ production and dead space can be calculated. The Capnostat 5 sensor as a mainstream gas analyzer includes a sample cell positioned in the breathing circuit through which a patient's inspiratory and expiratory gases flow. The LoFlo module, a sidestream type of gas analyzer, samples gases at 50 ml/min from a sampling port in an adapter placed in a breathing circuit or from a nasal or oral cannula. The gas then passes through a sampling tube to the

sample cell, where the gas components are measured. The combination adult CO₂ adapter/flow sensors with a partial rebreathing valve with periodic activation of the rebreathing valve allow pulmonary capillary blood flow and cardiac output to be calculated using the differential Fick method.

Intended Use of the Device: The intended use of the Philips NM3 monitor, Model 7900 is to provide:

- cardiac output monitoring via the method of partial rebreathing in adult patients receiving mechanical ventilation during general anesthesia and in the intensive care unit (ICU).
- spirometric, and carbon dioxide monitoring in neonatal, pediatric and adult patients during general anesthesia and in the intensive care unit (ICU) and the emergency department (ED). Separate combination CO₂/flow sensors are provided for adult, pediatric and neonatal use.
- continuous, non-invasive monitoring of functional arterial oxygen saturation and pulse rate in neonatal, pediatric and adult patients during both no motion and motion conditions and for patients who are well or poorly perfused during general anesthesia and in the intensive care unit (ICU) and the emergency department (ED).

The NM3 monitor Model 7900 and its sensors are intended to be used by trained operators when spirometric, capnographic, pulse oximetry, or cardiac output monitoring is indicated in the judgement of a physician.

The use of the NM3 monitor Model 7900 for cardiac output monitoring is contraindicated in patients in which a small rise (3-5 mmHg) in their arterial partial pressure of CO₂ level cannot be tolerated.

Technological Characteristics The NM3 monitor comprises the cleared Mercury module with the Capnostat 5 sensor for flow and carbon dioxide monitoring, the cleared LoFlo module for carbon dioxide monitoring and the cleared Masimo MX-1 module for pulse oximetry monitoring. It has been designed to include all of the functionality of the flow, carbon dioxide, cardiac output and pulse oximetry monitoring components of predicate NICO with MARS monitor.

The *NM3 monitor* uses flow sensors that are considered to be a fixed orifice, target flowmeters and as such the pressure drop is proportional to the square of the flow. Combination CO₂/flow sensors are available in three flow ranges that are tailored for neonates, pediatric patients and adults.

The *NM3 monitor* uses an infrared absorption (IR) technique for monitoring CO₂. The principle is based on the fact that CO₂ molecules absorb infrared light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO₂ concentration. Solid state CO₂ sensors (such as the Capnostat) use a beam splitter to simultaneously measure the IR light at two wavelengths: one which is absorbed by CO₂ and one which is not. The wavelength which is not absorbed by CO₂ is related to the intensity of the IR light source. Also, the IR light source is electronically pulsed in order to eliminate effects of changes in electronic components.

The *NM3 monitor* measures oxygen saturation and pulse rate with sensors that contain red and infrared light sources. Since oxygen saturated blood absorbs different amounts of light at each wavelength (red and infrared) as compared with unsaturated blood, the amount of light absorbed at each wavelength by the blood in each pulse can be used to calculate oxygen saturation. The light energy from red and infrared LEDs is beamed through a sample cell- a pulsating vascular bed, the patient's finger or toe for example. The remaining light energy not absorbed by the sample cell reaches a photodiode, on the opposing side of the sensor. The signal received by the photodiode is split into its red and infrared components, sampled, software filtered and displayed as a numerical value for oxygen saturation and as a waveform, the plethysmogram.

A variation on the traditional rebreathing methods, the non-invasive differential Fick partial re-breathing technique is used in the *NM3 monitor*. The change in VCO₂ and the change in end-tidal CO₂ in response to a change in ventilation is used to determine pulmonary capillary blood flow. This value is then corrected for the effect of shunt to determine cardiac output.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 2009

Mr. Kevin Mader
Manager of Quality Assurance and Regulatory Affairs
Respironics Novameterix, LLC
Critical Care
5 Technology Drive
Wallingford, Connecticut 06492

Re: K091459
Trade/Device Name: Philips NM3 Monitor
Regulation Number: 21 CFR 868.1850
Regulation Name: Monitoring Spirometer
Regulatory Class: II
Product Code: BZK
Dated: June 25, 2009
Received: June 30, 2009

Dear Mr. Mader:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

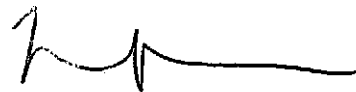
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

 For

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section ii Indications for Use

510(k) Number (if known): K 091459

Device Name: Philips NM3 Monitor

Indications for Use:

Intended Use:

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Prescription Use x
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The -Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 91459

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